REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 3, 5 to 16, and 20 to 24 are currently pending. Claims 4 and 17 to 19 were previously cancelled. Claims 3, 7 to 9 and 13 to 16 are currently withdrawn from consideration.

No claims are amended herein.

35 U.S.C. §102.

Claims 1, 2, 5, 6, 10 to 12, and 20 to 24, were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Grassetti (US 4,378,364), as evidenced by Barber (US 5,662,896) and Tagawa (Current Pharm. Design 6:681 (2000). Applicant traverses.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v. Kimberly-Clark Corp.,* 218 USPQ 781, 789 (Fed. Cir. 1983).

Grassetti '364 describes treatment of cancer patients with CPDS following surgery. The indications for use in such patients was post-surgical pain and appetite loss. Barber and Tagawa discuss an array of alternate techniques in cancer treatment including theory and problems associated with immunotherapy of cancers.

In previous Responses and briefs, Applicant has noted, and the Office had acknowledged, that Grassetti '364 does not teach at least the limitations of identifying an individual in need of immune response modulation or administration of thione-forming disulfides to one in need of immunomodulation. Now, the Office appears to argue that all missing limitations are inherent in the same previously cited art.

Not all patients undergoing chemotherapy are in need of immunomodulation. The Office argues that "all cancer patients are somewhat immune compromised and therefore would meet the limitation of 'patent in need thereof' herein. See, paragraph 0100 of the

specification herein. ... Those undergo chemotherapy and with pain are deemed to be immune compromised." These statements are unreasonable and without a basis in fact, as discussed below.

The rejections hinge on the argument that the current specification, at the first part of the first sentence in paragraph [0100], suggests that patients undergoing chemotherapy are all immunocompromised. However, this is an unreasonable interpretation of the paragraph. Paragraph [0100] is as follows, with emphasis added:

> **[0100]** TFDs can also be used to boost immune response in immunocompromised individuals, e.g., patients undergoing chemotherapy or individuals with genetic defects of immune function or the elderly. Patients undergoing chemotherapy may have lower than normal numbers of immune cells and the immune cells which are present may have had their functional activity compromised by the chemotherapy. In this case, it is beneficial to administer one or more TFD(s) to patients who are undergoing or have had chemotherapy treatment to boost their immune cell populations and functions.

The present rejections focus on, and misinterpret, part of one sentence, without regard to the context of the sentence as a whole, without regard for the context of the whole paragraph, and without consideration of the whole specification or the knowledge in the art. The cited statement does not expressly require that all chemotherapy patients are in need of immunomodulation. The statements of the paragraph actually objectively show that all chemotherapy patients are not inherently in need of immunomodulation. [See, *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); and *In re Oelrich* , 666 F.2d 578, 581 - 82, 212 USPQ 323, 326 (CCPA 1981).]

The Office apparently reads the first part of the first sentence in paragraph [0100] as a defining all patents undergoing chemotherapy as immunocompromised individuals. However, this inference is not supported by the facts. Applicant intended the phrase to teach that TFDs can be used to boost immune response in immunocompromised individuals, such as, e.g., immunocompromised patients undergoing chemotherapy. Look at the rest of the sentence. The logic of the Office's position would also require that "all elderly" are immunocompromised. This is not the case, as is known in the art, so the logic of the interpretation fails as well for chemotherapy patients.

The rest of the sentences in the paragraph contradict the logic of the Office's interpretation. The remaining sentences in the paragraph further clarify that not all patients undergoing chemotherapy are immunocompromised. "Patients undergoing chemotherapy may [or may not] have lower than normal numbers of immune cells [which does not necessarily amount to immunocompromise] and the immune cells which are present may [or may not] have had their functional activity compromised by the chemotherapy." The sentences following the cited sentence in the paragraph make it clear that Applicant understood that not all chemotherapy patients are immunocompromised.

The last sentence of the paragraph, refers, e.g., to that fraction of chemotherapy patients that do have immune cell functionality compromised. The last sentence suggests that this fraction of patients could benefit from administration of TFDs. "In this case [that subgroup of chemotherapy patients for whom immune functionality is lost], it is beneficial to administer one or more TFD(s) to patients who are undergoing or have had chemotherapy treatment to boost their immune cell populations and functions." In cases where cell populations or function have been compromised, it is beneficial to administer TFDs. In other cases, there is no suggestion to so administer the TFDs. The statement demonstrates that the Applicant envisioned that there are other cases of chemotherapy treated patients wherein the immune cell populations and function are not compromised, as stated in the prior sentence; thus a need for immune modulation is not suggested to be inherent in chemotherapy treatments.

As discussed above, review of the whole sentence, whole paragraph and full context of the cited statement makes it clear that the Applicant did not say that all chemotherapy patients are in need of immunomodulation. Therefore, the cited sentence fragment can does not support the rejection.

Again, the Office evidences the rejection with Barber and Tagawa. However, it is notable that the Action never actually mentions them in a fact-based argument in support of the rejections. This may be because Applicant has objectively shown, in several prior Responses, that Barber and Tagawa actually provide evidence proving the undeniable fact that, e.g., not all cancer or chemotherapy patients are in need of immunomodulation. For example, in Figure 1, Tagawa shows how an unmodulated immune system normally works

with, e.g., natural antigen presenting cells (APCs) activating cytotoxic T-lymphocytes (CTLs) to provide a normal CTL-mediated unmodulated immune response against a tumor *in vivo*. Barber, at the cited columns 1 and 2, makes it clear that cancer patients are not necessarily in need of immune modulation. For example, at column 1, line 35, Barber suggests that 30% of patients treated with surgery alone will have no recurrence. Chemotherapies and radiation therapies also have success without resort to immunomodulation. Even the specific invention of Barber does not include immune modulators in the treatment of cancer patients. Again, evidence from the Office's own references clearly demonstrates it is incorrect to assert that all cancer patients or patients undergoing chemotherapy are inherently in need of immune modulation.

The rejection appears to depend on the cursory statement of the Action that "[t]he fact that some cancer patients are treated without the employment of immunomodulation does not means those patients are not immune compromised. All cancer patients are somewhat immune compromised ... Those undergo chemotherapy ... are deemed to be immune compromised." However, these statements are conclusory and not fact-based, so can not stand as a basis for rejections. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006). The statement does not allege such patients are in need of immune modulation, as required by the claim. As discussed above, Applicant's specification and the Office's own references teach that not all cancer patients are immunocompromised, or and in need of immunomodulation. Because Grassetti '364 does not inherently teach administration of TFDs to patients in need of immunomodulation, the rejections for alleged anticipation must be withdrawn.

Grassetti '364 does not teach identifying an individual in need of immune response modulation. The claims include the limitation "identifying an individual in need of immune response modulation". The present Action does not even allege such a teaching in Grassetti '364, so fails to state a *prima facie* case.

Grassetti '364, at column 1, line 27, states that "cancer patients following surgery are treated to lessen pain, induce a feeling of well-being and increase appetite by administering a non-toxic reagent [TFDs]." Grassetti '364 teaches identification of patients

with loss of appetite and in pain as in need of TFDs. Such patients are not necessarily (inherently) those same patients that may be in need of immune response modulation.

The fact that this limitation is not taught by Grassetti '364 has been previously raised, but never clearly addressed in any Action of record.

The method claims are not merely reciting inherent characteristics of the TFD compositions. The present Action notes that *In re Swinehart*, 169 USPQ 226, holds that the "mere recitation of a newly discovered function or property, inherently possessed by the thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Applicant agrees. The Action then continues with: "[i]n the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter anticipated by the prior art." This statement does not accurately apply the facts of the present case to the holding of *In re Swinehart*.

In *Swinehart*, the claims were composition claims directed to old compositions of CaF_2 and BaF_2 wherein the composition claim included further limitations involving inherent properties of the old compositions. The court held that you can not claim an old composition based on newly discovered characteristics of the composition. Here, Applicant is not claiming TFDs, with or without previously unknown inherent characteristics. The present claims are directed to new methods of using the previously known TFDs. Applicant notes that 35 U.S.C. § 101 states (emphasis added) that:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Here, Applicant is merely pursuing claims to a useful improvement to a method of using a composition, as is proper.

Because the rejection is not based on facts, Applicant is not sure what may be the basis of the rejections. Applicant is not sure what "ultimate utilities" or "biochemical intermediates" are being referred to in the rejection. However, it is certain that the claims are not directed to "claimed compounds" with "old and well known" ultimate utilities. As

discussed above, no prior art reference teaches utility in modulating immune responses or administering TFDs to individuals in need of immune response modulation.

Applicant is claiming, e.g., new methods of using TFDs, not TFD compositions based on inherent characteristics. The methods were not actually or inherently known in the prior art. All limitations of the claims are not taught or inherent in the teachings of the cited reference. Applicant respectfully requests withdrawal of the rejections for alleged anticipation by Grassetti '364.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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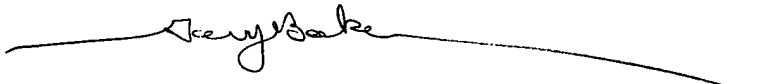
Respectfully submitted,



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Attachments:

1) A transmittal sheet; and,
2) A receipt indication postcard.